15 510(K) SUMMARY

NOV 20 2008

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Per 21 CFR 807.92)

General Company Information

Name:	Alveolus Inc.
Contact:	Tony Alexander Executive Vice President
Address:	9013-A Perimeter Woods Drive Charlotte, NC 28216
Telephone:	(704) 926-4846
Fax:	(704) 926-4895

Date Prepared August 8, 2008

15.1 General Device Information

Product Name: AERO™ Tracheobronchial Stent Technology System

Classification: "Tracheal Prosthesis", Product code: JCT
21 CFR 878.3720 - Class II

15.2 Predicate Devices

Alveolus, Inc. TB-STS™ Tracheobronchial Stent Technology System [510(k) Numbers K062511]

Boston Scientific Corp. Inc. Ultraflex™ Tracheobronchial Stent Technology System [501(k) Number K963241]

Rusch International Polyflex Stent Kit [510(k) Number K013266]

15.3 Description

The Alveolus AERO™ is comprised of two components: the radiopaque stent and the delivery system. The nitinol stent is completely covered with a biocompatible polyurethane membrane and is self-expanding. The stent expansion results from the physical properties of the metal and the proprietary geometry. The stent is designed with a slightly larger diameter near the distal and proximal ends to minimize the possibility of migration (2mm for bronchus stent sizes and 3mm for tracheal stent sizes). The stent ends are slightly vaulted inwardly in order to minimize possible airway injury from the stent edges. The overall stent geometry is designed to maintain a constant length over the entire range of possible diameters. As a result of this unique design the stent has virtually no foreshortening, thus facilitating the selection of the appropriate stent length.

15.4 Intended Use (Indications)

The Alveolus AERO™ is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

15.5 Substantial Equivalence

This submission supports the position that the Alveolus Tracheobronchial Stent is substantially equivalent to a number of previously cleared devices, including the Alveolus TB-STS™ Tracheobronchial Stent Technology System [510(k) K062511], the Boston Scientific Corp. Inc. Ultraflex™ Tracheobronchial Stent Technology System [501(k) Number K963241], the Rusch International Polyflex Stent Kit [510(k) Number K013266] and the Novatech S.A. Endoxane® Stent [510(k) Number K971509].

The single-patient-use components of the AERO™ Tracheobronchial Stent Technology System are provided non-sterile.

15.6 Conclusions

Alveolus Inc. believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the Alveolus Tracheobronchial Stent. The materials from which the Alveolus device is fabricated have an established history of use in clinical applications, and the devices produced by Alveolus have been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Tony Alexander
Executive Vice President
Alveolus, Incorporated
9013 Perimeter Woods Drive, Suite A
Charlotte, North Carolina 28216

NOV 20 2008

Re: K082284
Trade/Device Name: AERO™ Tracheobronchial Stent Technology System
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal Prosthesis
Regulatory Class: II
Product Code: JCT
Dated: October 24, 2008
Received: October 27, 2008

Dear Mr. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the device's labeling immediately following the Indications for Use section, and on the carton pouch labeling in a font-size that is easy to read:

Warning: The safety and effectiveness of this device for use in the vascular system has not been established and can result in serious harm and/or death.

Furthermore, the indication for tracheal use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

12 INTENDED USE STATEMENT

510(k) Number (if known):

Device Name: Alveolus AERO™ Tracheobronchial Stent Technology System

Indications For Use:

The Alveolus AERO™ Tracheobronchial Stent Technology System is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

Prescription Use_____X____ **AND/OR** **Over-The-Counter Use_____**
(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

10(k) Number: K082284